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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,967	11/16/2001	Ying-Fei Wei	PF268D1C1	7962

22195 7590 08/14/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
SPECTOR, LORRAINE

ART UNIT	PAPER NUMBER
1647	4

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Part III: Detailed Office Action

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to nucleic acids, vector, host cells, and expression of proteins, classified in class 536, subclass 23.5 or class 435, subclass 69.1, for example.

III. Claim 17, drawn to hHSP antagonist, classification dependent upon species .

IV. Claim 18, drawn to hHSP agonist, classification dependent upon species .

V. Claim 19, drawn to a method of treatment using hHSP protein, classified in class 514, subclass 2.

VI. Claim 20, drawn to a method of treatment using DNA, classified in class 514, subclass 44.

VII. Claim 21, drawn to a method of treatment using hHSP antagonist, classification dependent upon species.

VIII. Claim 22, drawn to a diagnostic method of detecting nucleic acid mutation, classified in class 435, subclass 6.

IX. Claim 23, drawn to a diagnostic protein assay, classified in class 435, subclass 7.1.

X. Claim 24, drawn to assay for agonists/antagonists of hHSP, classified in class 435, subclass 7.2.

XI. Claims 25-41, 44-67 and 70-76, drawn to antibodies, classified in class 530, subclass 387.9.

XII. Claims 42, 43, 68 and 69, drawn to immunoassays, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell,

as recited in claim 12. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The products of each of Inventions I-IV are independent and distinct, each being of distinct physical and chemical structure, activity, and each being capable of separate manufacture and use and requiring separate searches. Further, the products of Inventions III and IV are mutually exclusive, being defined by mutually exclusive activities.

The products of Invention I are independent and distinct from the methods of each of Inventions V and VII-X and XII, wherein the products may be neither made by nor used in the methods. The methods of Inventions I , and V-X and XII are independent and distinct, wherein each respective method has different starting and ending materials and purposes, and requires substantively different method steps.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products may be used as hybridization ant production of protein in bacterial cells.

Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein may be used for *in vitro* assays, or for the production of antibodies.

The products of Invention II are independent and distinct from the methods of each of Inventions VI-VIII and XII, wherein the products may be neither made by nor used in the methods.

Although the products of Invention II may be detected by the method of invention IX, the two are nonetheless distinct because the means of detection does not in any way define the product detected, and because the product may not be made by the method.

The polypeptide of Invention II is related to the antibody of Invention XI by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

The products of Invention III are independent and distinct from the methods of each of Inventions V, VI, VIII, and IX wherein the products may be neither made by nor used in the methods.

The products of Invention III are related to each of the methods of Inventions VII and as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antagonist may be used in either of the distinct processes of inventions VII or X.

The products of Invention IV are independent and distinct from the methods of each of Inventions V-IX wherein the products may be neither made by nor used in the methods.

Although the products of Inventions III or IV may be detected by the methods of invention X, the products are nonetheless distinct from the method because the means of detection does not in any way define the product detected as evidenced by the fact that the same method can detect the two mutually exclusive groups of products, and because the products may not be made by the

method.

The nucleic acid of Invention I is distinct from and unrelated to the antibody of Invention XI because they are physically and functionally distinct chemical entities which share neither structure nor function. Also, neither is required for the manufacture of the other. The method of Invention I is distinct from and unrelated to the antibody of Invention XI because the antibody may be neither made by nor used in the method.

Invention XI is drawn to a product that minimally overlaps with the products of Inventions III and IV. However, Invention XI is nonetheless separate and distinct from Inventions III and IV because neither of the latter requires antibodies, and because numerous of the antibodies of Invention XI would not fall into Invention III or IV. Accordingly, non-coextensive searches are required, and restriction is proper.

Invention XI is distinct from each of Inventions V-X, wherein the antibody of Invention I is neither made by nor required for the methods of Inventions V-X.

Inventions XI and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used in any of a number of materially distinct processes, such as those of Invention X.

Inventions I-IV are distinct from and unrelated to the method of Invention XII, wherein the products of Inventions I-IV are neither made by nor used in the methods of Invention XII, and wherein each does not require the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Advisory Information:

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

Lorraine Spector, Ph.D.
Primary Examiner

8/13/03

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Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	

ART UNIT	PAPER NUMBER
	4

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire One month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-76 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-76 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/405